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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,814

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Lucien A. Couvillon JR.

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MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER

DEMILLE, DANTON D

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/645,814	Applicant(s) COUVILLON, LUCIEN A.	
	Examiner Danton DeMille	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16, 18 and 20-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16, 18 and 20-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there appears to be no clear written support in the original disclosure to support the actuators to be in adjacent rows offset circumferentially with respect to one another. Since there appears to be no support in the original disclosure it is also not clear how this new feature is now critical to the device and how it provides any particular advantage over the prior art.

Claim Rejections - 35 USC § 112

Claims 1-14, 16, 18, 20-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Because there is no support in the original disclosure for the now claimed arrangement of the actuators to be in rows that are offset circumferentially with respect to one another it is not clear what applicant is attempting to comprehend by this language. What would comprehend the claimed “offset” relationship?

To any extent the claims are understood and appear to be supported by a clear and complete disclosure the following appears to be appropriate.

Claim Rejections - 35 USC § 103

Claims 1-14, 16, 18, 20-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown III in view of Shabty et al., Madden et al., Hegde et al. and Barak et al.

Brown teaches applicant's system for exerting a compressive force on an exterior treatment portion of a user's body to assist the return of blood to the heart from the extremities by compressing the veins and relying on the venous valves to favor one-way flow so that the heart need not do all the work of perfusion. The device includes a covering member for covering the treatment portion comprising circumferential bands of an electroactive polymer (EAP) actuator operably connected to the covering for compressing the treatment portion of the user's body. Brown gives examples of the polymers that are useful in his invention however, Brown's invention is not restricted to any one of the given examples. Brown does not want to be limited to such details. Other obvious equivalent alternative polymers would have been an obvious modification.

Applicant's own disclosure admits that the details of the EAP are well known. Such details have already been provided by the prior art. The details of the electroactive polymer actuator are well known as admitted by applicant's disclosure in the paragraph beginning on the bottom of page 5 and continuing to page 6. "Additional information regarding the construction of such actuators, their design considerations and the materials and components that may be deployed therein can be found, for example, in U.S. Pat. No. 6,249,076..." The noted prior art patent 6,249,076 is Madden which teaches the details of the electroactive polymer actuator including a counter electrode and an electrolyte-containing region.

Both Brown and applicant's invention are not limited to the details of the EAP. Such details are provided by the prior art such as Madden. As admitted by applicant, it would have

been obvious to one of ordinary skill to modify Brown to use any conventional EAP such as that taught by Madden as further taught by applicant as an obvious equivalent alternative EAP for performing the same function. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

The Brown device is for applying compressive forces to parts of the body to stimulate blood flow. The Brown device is a stocking/garment that is capable of being placed on a portion of the body including a thigh and then having stimulus applied thereto to stimulate blood flow (column 1, lines 10-16). Brown teaches that prior art stocking merely constricts the musculature of the lower extremity but does not mimic the pulsatile milking action of the leg muscles upon the veins which enhance venous blood flow back to the heart (column 1, lines 54-58). "There is need to provide a sequential application of compressive forces for squeezing or constricting the muscles thereof to prevent stasis of blood with resultant thrombus formation in the leg veins and pulmonary emboli associated therewith" (column 2, lines 37-41). Clearly Brown's device is for sequential compressions of the extremities to help blood flow back to the heart in patients that have compromised circulatory systems.

The Shabty device is also for applying compressive forces to parts of the body to stimulate blood flow. The Shabty device is a wrap that is placed on a portion of the body in segments including the ankle, calf, thigh, and buttocks sections. Tissue compression is applied to each component sequentially (paragraph 13). Shabty also teaches the apparatus producing the tissue compression enhancing blood flow may also be applied uniquely on every other heart beat, every second beat, or every third beat, depending on which sequence produces the most augmentation (paragraph 14). The compressions are a timed, pressurized pulse of blood back toward the heart when the heart is normally resting between beats. Therefore the pressurized

pulse of blood flow back toward the heart does not occur at the same time the heart is trying to product a pressurized pulse out toward the extremities i.e., “counterpulsation”. Clearly Shabty already teaches the advantage of applying compressive forces on the treatment portion of the body and takes it a step further by synchronizing the compressive forces with the heartbeat to improve blood flow back toward the heart without opposing the hearts efforts.

Hegde is also cited to teach that using EAP in the form of a wrap for the treatment of enhancing blood flow back to the heart when synchronized with the heartbeat is not a foreign idea. Hedge teaches, “FIG. 62 illustrates a comparison of arterial pressure and a corresponding EKG readout when an embodiment of an EAP actuated vascular assist system is providing augmentation is in a counterpulsation manner” (paragraph 244, lines 6-10). “In order to actuate the EAP elements to provide counterpulsation the pump and pacing controller 415 calculates the Q-T interval for the heart rate and triggers at the appropriate moment based on the response time of the EAP actuated system being used” (paragraph 247, lines 4-9). Therefore Hegde is an additional reference that teaches it is well known to use an EAP device to provide a counterpulsation apparatus for exerting a compressive force on a treatment portion of the user’s body in synchrony with the heart beat of the user.

Barak also teaches a system for exerting a compressive force on the exterior treatment portion of the user’s body including a covering member with a plurality of actuators 2 in adjacent rows. The adjacent rows are offset circumferentially with respect to one another. There appears to be no unobviousness to the exact arrangement of the compressive circumferential rows.

It would have been obvious to one of ordinary skill in the art to modify Brown and use the details of the EAP as taught by Madden as an obvious equivalent alternative means for doing the same thing as further suggested by applicant’s admission and to use the device in synchrony

with the heart beat as taught by Shabty to provide the added benefit of synchronizing compressions with the heart beat to augment blood circulation by timing it with the heart to help with the return of blood flow back to the heart. Hegde is also provided to teach that it is well known to use an EAP device in counterpulsation to augment blood flow back to the heart timed with the heart beat. It would have been obvious to one of ordinary skill in the art to further modify Brown to arrange the actuators in offset circumferential rows as taught by Barak as an obvious equivalent arrangement in order to more evenly distribute the pressures on the body.

Double Patenting

Claims 1-14,16,17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/373,940. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim identical subject matter.

Regarding claim 1, the "compressor" 102 of claim 1 of the copending claims (hereon referenced as "reference B") is defined to comprise receiver 108 of claim 6 that covers the exterior treatment portion of the user's body and therefore comprehends the claims. This "covering member" is claimed to have an electroactive polymer (EAP) actuator coupled to it. Due to the fact that Claim 2 of reference B states that an electrical driver is operably connected to the EAP actuator, the EAP actuator is operably connected to the covering member.

Regarding claims 3,5 see claims 8,10 of reference B.

Regarding claim 6, the computing device of claim 5 is said to be selected from a variety of computing devices, as well as a dedicated special-purpose electronic control device. This "controller" is claimed to provide a drive signal to actuate the EAP actuator.

This is a provisional obviousness-type double patenting rejection because the

conflicting claims have not in fact been patented.

Claims 18, 20-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/373,940 in view of Brown and Shabty et al.

Regarding claims 18, 20, 25 the copending claims lack a covering member that comprises a fabric garment. Brown 111 discloses a system comprising a garment-covering member 10 coupled to a plurality of polymer strips 120 that contract upon the delivery of an electrical stimulus (col. 4 lines 26-42) and thus constitute a plurality of electroactive polymer (EAP) actuators. The covering member is further said to be made of an elastomeric, or flexible material (col. 5 lines 35-40). It would have been obvious to one of ordinary skill at the time the invention was made to provide the apparatus of the copending claims with a fabric garment material to facilitate the identical claimed function to an exterior portion of a user's body.

Regarding claim 21, the actuators of Brown are further said to be woven into the covering member (col. 5 lines 35-36).

Regarding claims 22-24, the copending claims lack incorporation of actuators into a garment covering member. The actuators are said to be incorporated into the covering member of Brown by weaving it into the covering material, placing them in pockets, or attaching them directly to it (col. 5 lines 32-35). A pocket constitutes multiple layers of fabric. Although the reference does not explicitly state that the actuators are stitched or glued into the covering member, it would have been obvious to provide incorporate the actuators of the copending claims by an alternate method of incorporation since it would result in an identical objective.

Regarding claims 26,27, the Brown, 111 reference lacks a heart beat sensor. Shabty et al. discloses a counterpulsation device that comprises an EKG sensor (paragraph 52), a device that

measures the sinus rhythm, or electrical conductance of the head. Shabty et al teaches the advantage of timing the limb compression with the heart rate to increase the affects of blood flow return. Thus, the device provides a drive signal based on the head sensor signal. It would have been obvious to one of ordinary skill at the time the invention was made to provide the counterpulsation device copending claims in view Brown, 111 with a head rate sensor as taught by Shabty et al in order to sense the sinus rhythm of the head and to cause simultaneous compression.

Regarding claims 28,29 the copending claims in view of Brown, 111 lacks a sensor for a biological characteristic indicative of an efficaciousness of the counterpulsation pressure. The counterpulsation device of Shabty et al comprises an EKG 100 and a pulse oximetry measurement system 102 to obtain the user's blood pressure and head rate. A plethysmograph is included (paragraph 52) to determine the circulatory capacity, or blood flow, of a limb. The timing of the inflation and deflation of the covering member is coordinated with the patient's natural blood flow (paragraph 62). In other words, a drive signal is provided by a controller based on the biological sensor signal received. It would have been obvious to one of ordinary skill at the time the invention was made to provide the device of the copending claims in view of Brown, 111 with the aforementioned sensor for sensing a biological characteristic as taught by Shabty et al in order to provide a means to obtain a user's vital information and to apply appropriate treatment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974. The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

26 March 2008

/Danton DeMille/
Danton DeMille
Primary Examiner
Art Unit 3771